K072741

510(k) Summary
Pre~Va Vaginal Lubricant

JUL 16 2008

I. General Information on Submitter

Address:	INGfertility, LLC (Subsidiary of Bio-Origyn, LLC) 17206 S. Spangle Creek Rd. Valleyford, WA 99036 USA
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Email:	dclifton@ingfertility.com
Contact Person:	G. Dennis Clifton, Pharm.D.
Date Prepared:	March 18, 2008

II. General Information on Device

Proprietary Name:	Pre~Va Vaginal Lubricant
Classification Name:	lubricant, patient, vaginal, latex compatible (21 CFR 884.5300, Product Code NUC)

III. Predicate Devices

Predicate Device	510(k) control #
Pre' Vaginal Lubricant	K051436

IV. Description of Device

This product is a non-sterile, water-based personal lubricant formulated to supplement the body's own natural lubricating fluids. Pre~Va is used to lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices including those used in fertility interventions. It is also used as a personal lubricant to supplement the body's own natural lubricating fluids and to enhance the comfort of intimate sexual activity. The formulation does not harm sperm function and has a pH and osmolarity that are physiologic ("balanced") to that of fertile cervical mucus and semen. The product is compatible with latex and polyurethane condoms. Following is the ingredient list for Pre~Va Vaginal Lubricant:

Ingredients
Water
Hydroxyethylcellulose, NF
Pluronic 127, NF
Sodium Chloride, USP
Arabinogalactan
Sodium Phosphate
Carbopol 934P, NF
Methyl Paraben, USP
Sodium Hydroxide, NF
Potassium Phosphate

V. Intended Use

- To lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices including those used in fertility interventions. Pre~Va may be applied directly to the device or may be deposited intravaginally using the applicator, prior to the insertion of diagnostic or therapeutic devices used in fertility interventions
- As a personal lubricant Pre~Va supplements the body's own natural lubricating fluids, to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. Pre~Va is safe for use by couples who are trying to conceive and may be applied to vaginal or penile tissues for lubrication and moisturization purposes. It is compatible with latex and polyurethane condoms.

VI. Technological Characteristics of Device Compared to Predicate Device
All of the technological characteristics of Pre~Va are identical to the predicate device.

VII. Summary of Performance Data
The performance data of Pre~Va are identical to the predicate.

VIII. Conclusion
Pre~Va Vaginal Lubricant is safe for its intended use and substantially equivalent to the predicate device Pre' Vaginal Lubricant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2008

Dennis Clifton, Pharm.D.
Vice President
INGfertility, LLC
17206 South Spangle Creek Road
VALLEYFORD WA 99036

Re: K072741
Trade/Device Name: Pre-Va Vaginal Lubricant
Regulatory Class: 21 CFR 884.5300
Regulation Number: Condom
Product Code: NUC
Dated: July 1, 2008
Received: July 8, 2008

Dear Dr. Clifton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please ~~contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one~~ of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
~~Other~~		~~240-276-0100~~

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072741

Device Name: Pre~Va Vaginal Lubricant

Indications for Use:

- To lubricate vaginal tissues to facilitate entry of diagnostic or therapeutic devices including those used in fertility interventions. Pre~Va may be applied directly to the device or may be deposited intravaginally using the applicator, prior to the insertion of diagnostic or therapeutic devices used in fertility interventions.
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Prescription Use _____ AND/OR Over-The-Counter Use __X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K072741